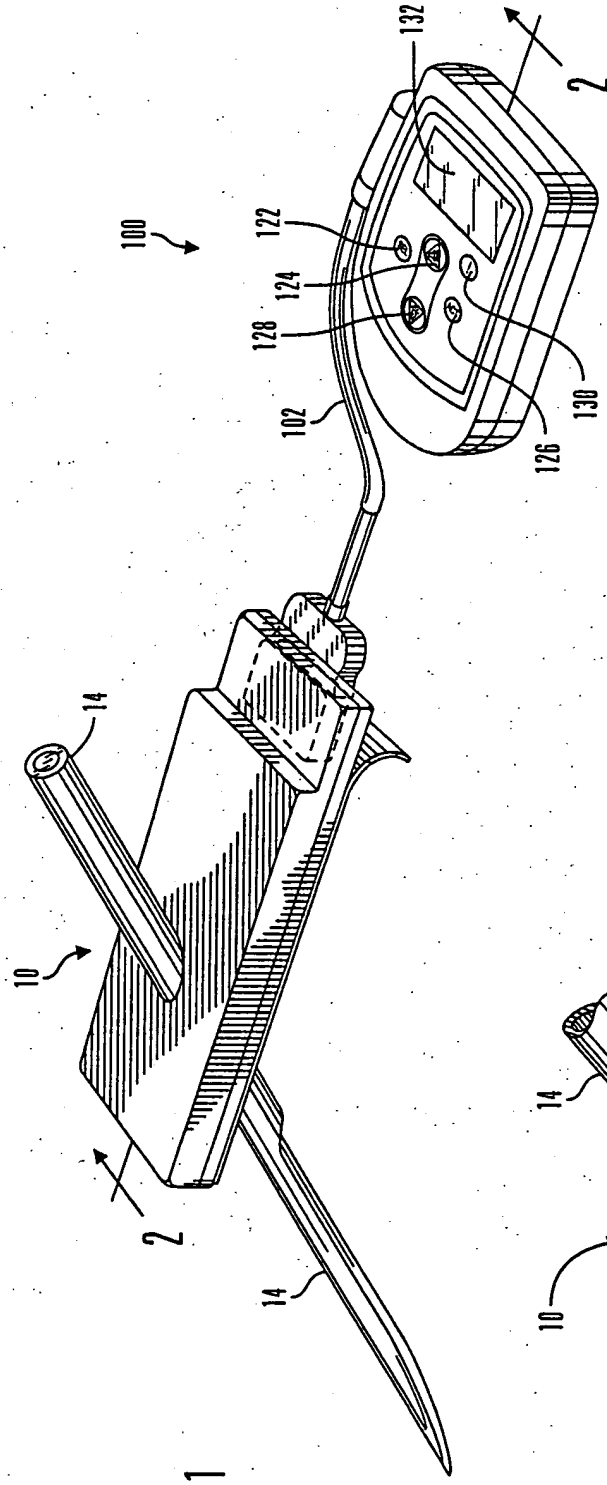

100
132
2
122
124
128
130
126
102
14
10
2
14

FIG. 1

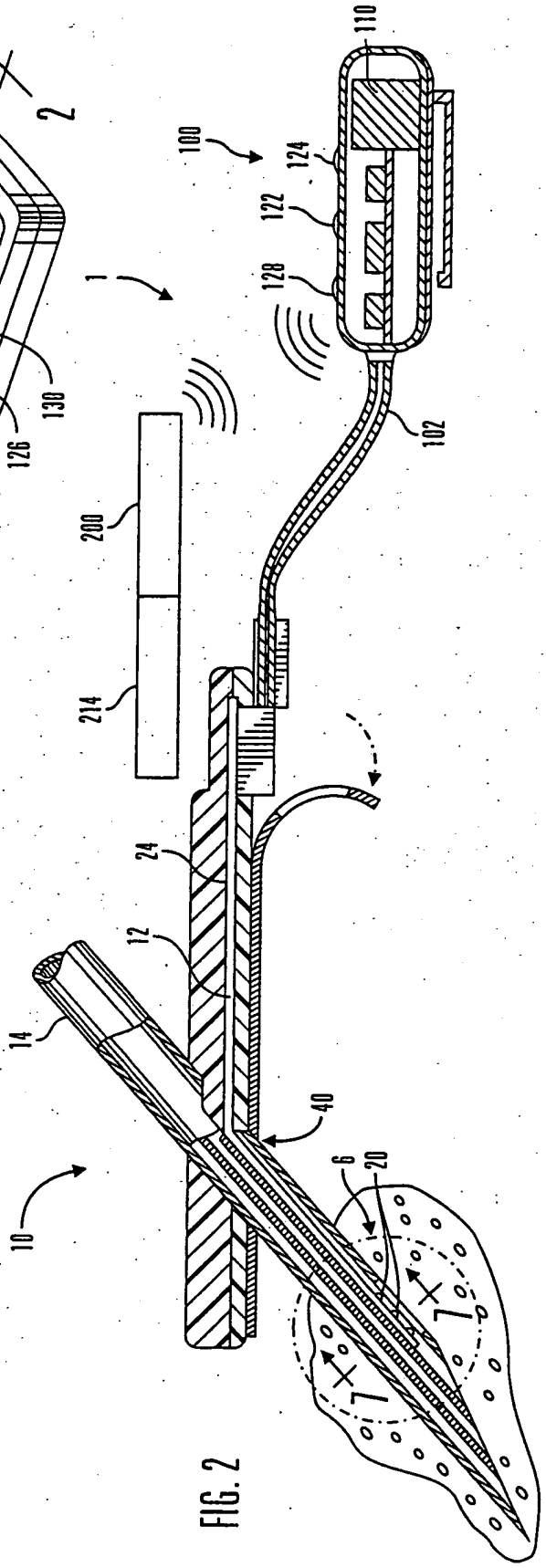

110
100
124
122
128
1
102
200
214
24
12
14
40
10
6
20
7
7

FIG. 2

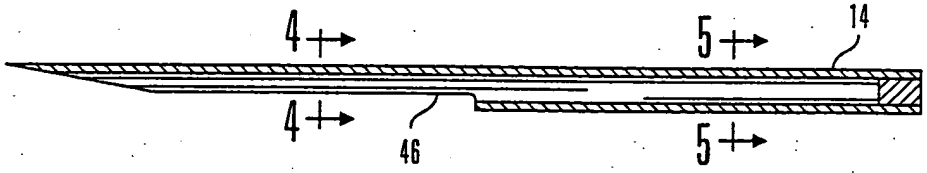



FIG. 3

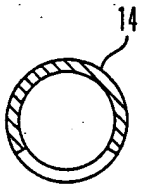



FIG. 4

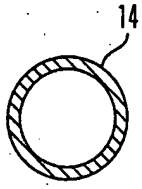



FIG. 5

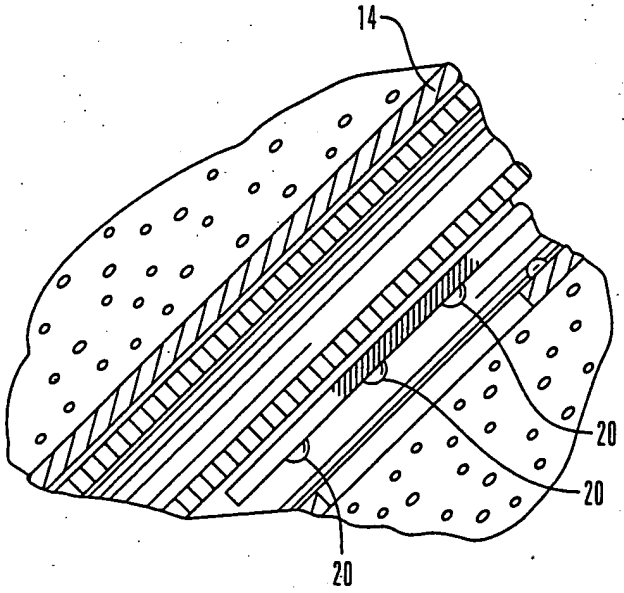



FIG. 6

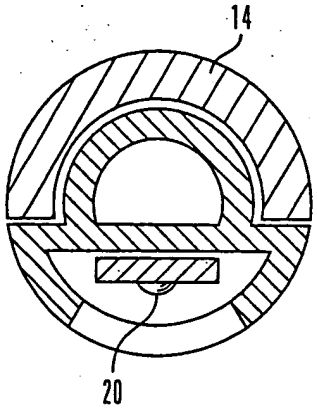



FIG. 7

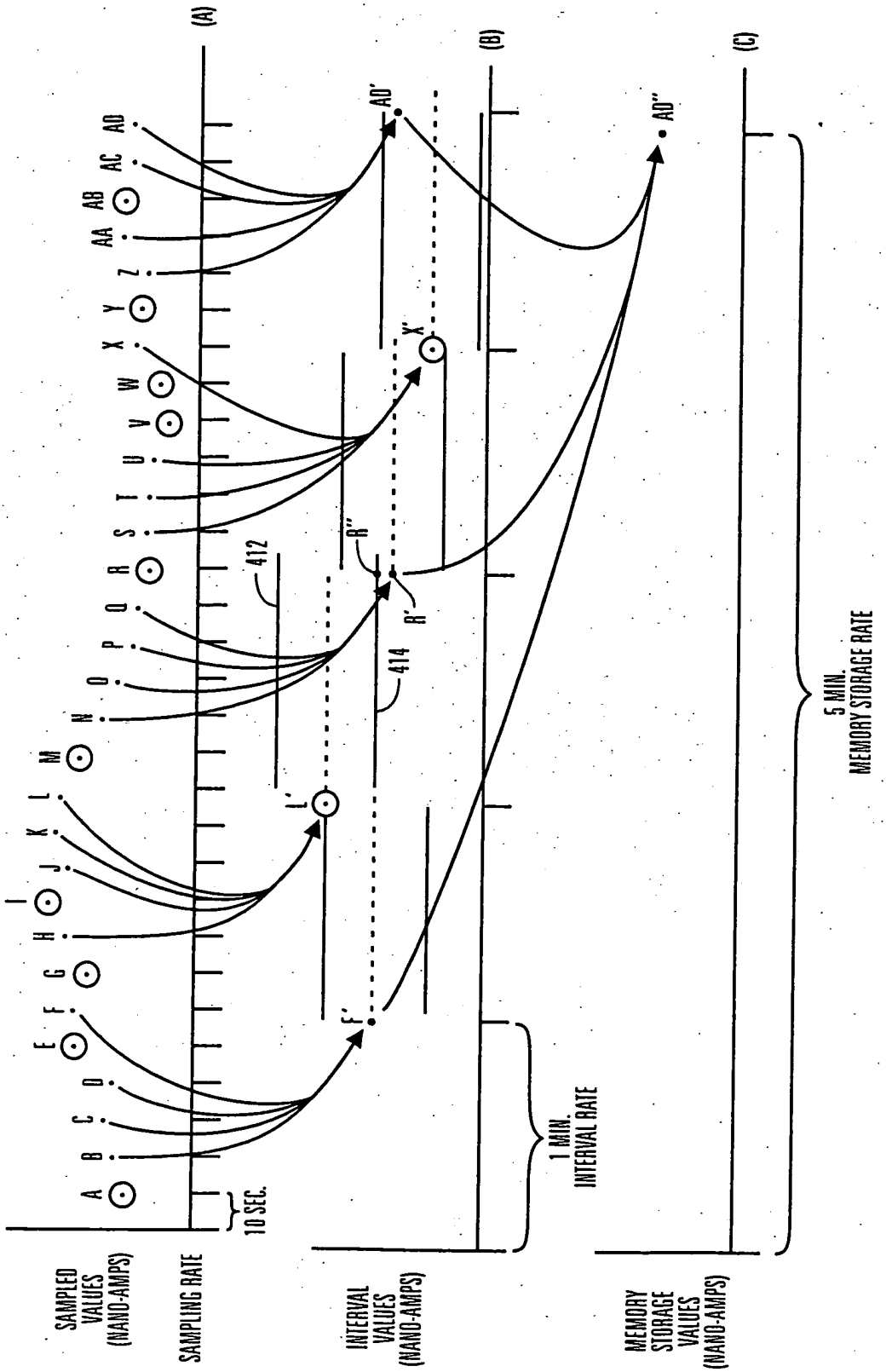

(A)
(B)
(C)
A
B
C
D
E
F
G
H
I
J
K
L
M
N
O
P
Q
R
S
T
U
V
W
X
Y
Z
AA
AB
AC
AD
AD'
AD''
X'
R''
R'
L'
F'
412
414
10 SEC.
1 MIN.
INTERVAL RATE
5 MIN.
MEMORY STORAGE RATE
SAMPLED VALUES (NANO-AMPS)
SAMPLING RATE
INTERVAL VALUES (NANO-AMPS)
MEMORY STORAGE VALUES (NANO-AMPS)

FIG. 8

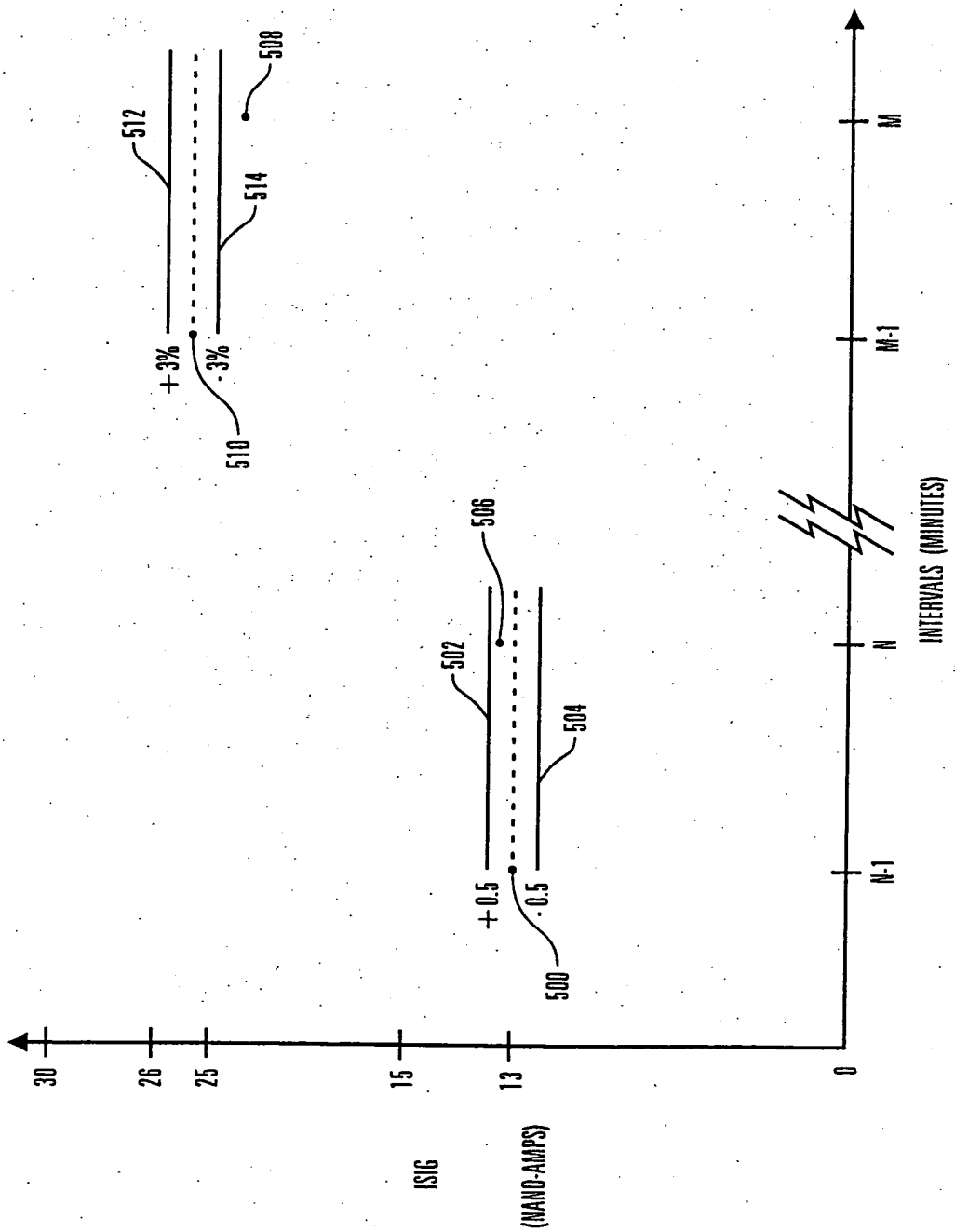
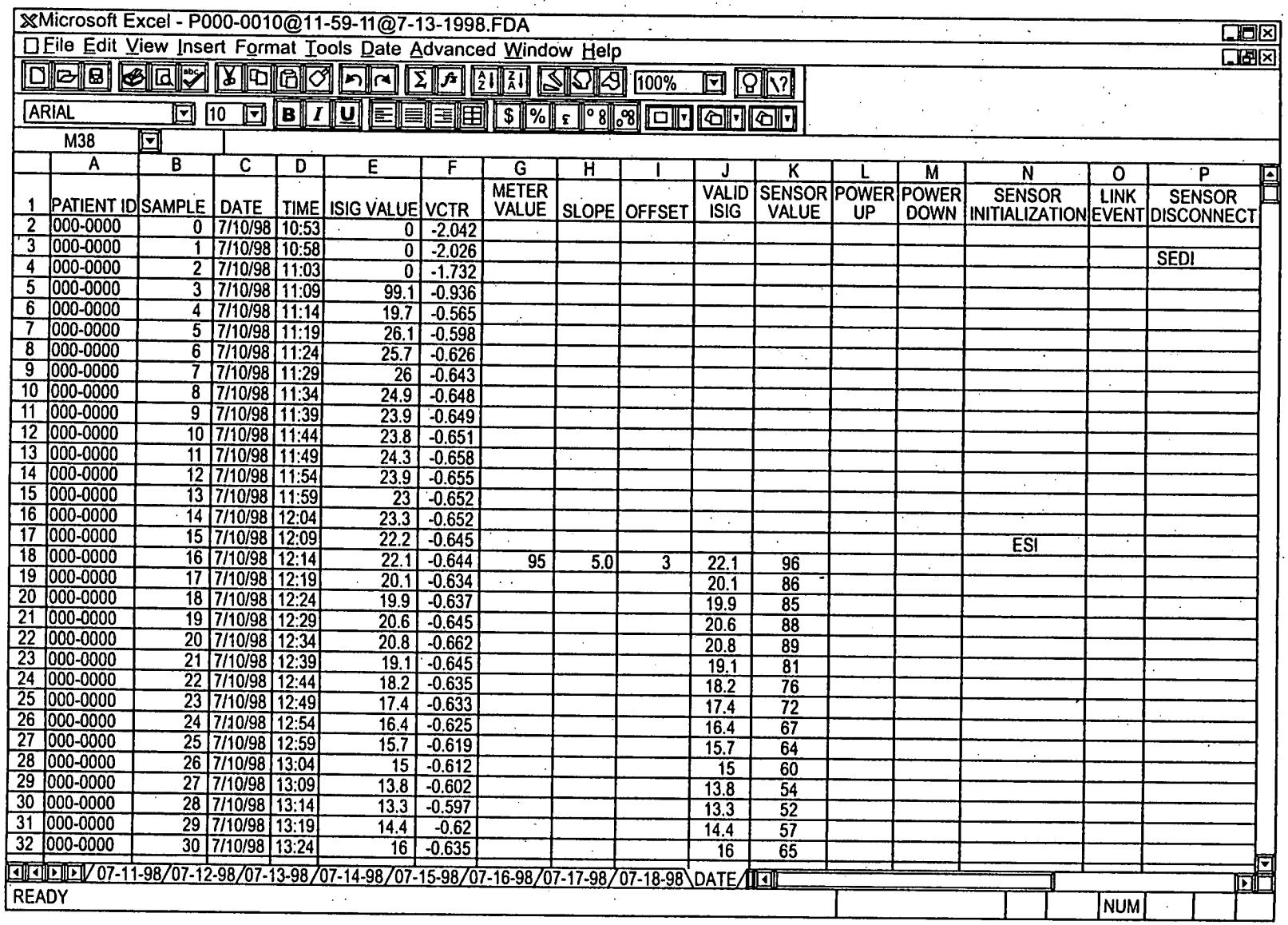

30
26
25
15
13
0
ISIG
(NANO-AMPS)
INTERVALS (MINUTES)
N-1
N
M-1
M
+0.5
-0.5
+3%
-3%
500
502
504
506
508
510
512
514

FIG. 9


Microsoft Excel - P000-0010@11-59-11@7-13-1998.FDA

File Edit View Insert Format Tools Date Advanced Window Help

ARIAL 10 100%

M38

| | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | PATIENT ID | SAMPLE | DATE | TIME | ISIG VALUE | VCTR | METER VALUE | SLOPE | OFFSET | VALID ISIG | SENSOR VALUE | POWER UP | POWER DOWN | SENSOR INITIALIZATION | LINK EVENT | SENSOR DISCONNECT |
| 2 | 000-0000 | 0 | 7/10/98 | 10:53 | 0 | -2.042 | | | | | | | | | | |
| 3 | 000-0000 | 1 | 7/10/98 | 10:58 | 0 | -2.026 | | | | | | | | | | |
| 4 | 000-0000 | 2 | 7/10/98 | 11:03 | 0 | -1.732 | | | | | | | | | | SEDI |
| 5 | 000-0000 | 3 | 7/10/98 | 11:09 | 99.1 | -0.936 | | | | | | | | | | |
| 6 | 000-0000 | 4 | 7/10/98 | 11:14 | 19.7 | -0.565 | | | | | | | | | | |
| 7 | 000-0000 | 5 | 7/10/98 | 11:19 | 26.1 | -0.598 | | | | | | | | | | |
| 8 | 000-0000 | 6 | 7/10/98 | 11:24 | 25.7 | -0.626 | | | | | | | | | | |
| 9 | 000-0000 | 7 | 7/10/98 | 11:29 | 26 | -0.643 | | | | | | | | | | |
| 10 | 000-0000 | 8 | 7/10/98 | 11:34 | 24.9 | -0.648 | | | | | | | | | | |
| 11 | 000-0000 | 9 | 7/10/98 | 11:39 | 23.9 | -0.649 | | | | | | | | | | |
| 12 | 000-0000 | 10 | 7/10/98 | 11:44 | 23.8 | -0.651 | | | | | | | | | | |
| 13 | 000-0000 | 11 | 7/10/98 | 11:49 | 24.3 | -0.658 | | | | | | | | | | |
| 14 | 000-0000 | 12 | 7/10/98 | 11:54 | 23.9 | -0.655 | | | | | | | | | | |
| 15 | 000-0000 | 13 | 7/10/98 | 11:59 | 23 | -0.652 | | | | | | | | | | |
| 16 | 000-0000 | 14 | 7/10/98 | 12:04 | 23.3 | -0.652 | | | | | | | | | | |
| 17 | 000-0000 | 15 | 7/10/98 | 12:09 | 22.2 | -0.645 | | | | | | | | ESI | | |
| 18 | 000-0000 | 16 | 7/10/98 | 12:14 | 22.1 | -0.644 | 95 | 5.0 | 3 | 22.1 | 96 | | | | | |
| 19 | 000-0000 | 17 | 7/10/98 | 12:19 | 20.1 | -0.634 | | | | 20.1 | 86 | | | | | |
| 20 | 000-0000 | 18 | 7/10/98 | 12:24 | 19.9 | -0.637 | | | | 19.9 | 85 | | | | | |
| 21 | 000-0000 | 19 | 7/10/98 | 12:29 | 20.6 | -0.645 | | | | 20.6 | 88 | | | | | |
| 22 | 000-0000 | 20 | 7/10/98 | 12:34 | 20.8 | -0.662 | | | | 20.8 | 89 | | | | | |
| 23 | 000-0000 | 21 | 7/10/98 | 12:39 | 19.1 | -0.645 | | | | 19.1 | 81 | | | | | |
| 24 | 000-0000 | 22 | 7/10/98 | 12:44 | 18.2 | -0.635 | | | | 18.2 | 76 | | | | | |
| 25 | 000-0000 | 23 | 7/10/98 | 12:49 | 17.4 | -0.633 | | | | 17.4 | 72 | | | | | |
| 26 | 000-0000 | 24 | 7/10/98 | 12:54 | 16.4 | -0.625 | | | | 16.4 | 67 | | | | | |
| 27 | 000-0000 | 25 | 7/10/98 | 12:59 | 15.7 | -0.619 | | | | 15.7 | 64 | | | | | |
| 28 | 000-0000 | 26 | 7/10/98 | 13:04 | 15 | -0.612 | | | | 15 | 60 | | | | | |
| 29 | 000-0000 | 27 | 7/10/98 | 13:09 | 13.8 | -0.602 | | | | 13.8 | 54 | | | | | |
| 30 | 000-0000 | 28 | 7/10/98 | 13:14 | 13.3 | -0.597 | | | | 13.3 | 52 | | | | | |
| 31 | 000-0000 | 29 | 7/10/98 | 13:19 | 14.4 | -0.62 | | | | 14.4 | 57 | | | | | |
| 32 | 000-0000 | 30 | 7/10/98 | 13:24 | 16 | -0.635 | | | | 16 | 65 | | | | | |

07-11-98 / 07-12-98 / 07-13-98 / 07-14-98 / 07-15-98 / 07-16-98 / 07-17-98 / 07-18-98 \ DATE /

READY NUM

FIG. 10

U.S. EXPRESS MAIL NO. EV060046999US
Foley & Lardner – 310-277-2223
Atty: Ted R. Rittmaster
Title: REAL TIME SELF-ADJUSTING CALIBRATION ALGORITHM
Inventor(s): John J. Shin et al.
DOCKET NO.: 047711-0335
Sheet 5 of 18

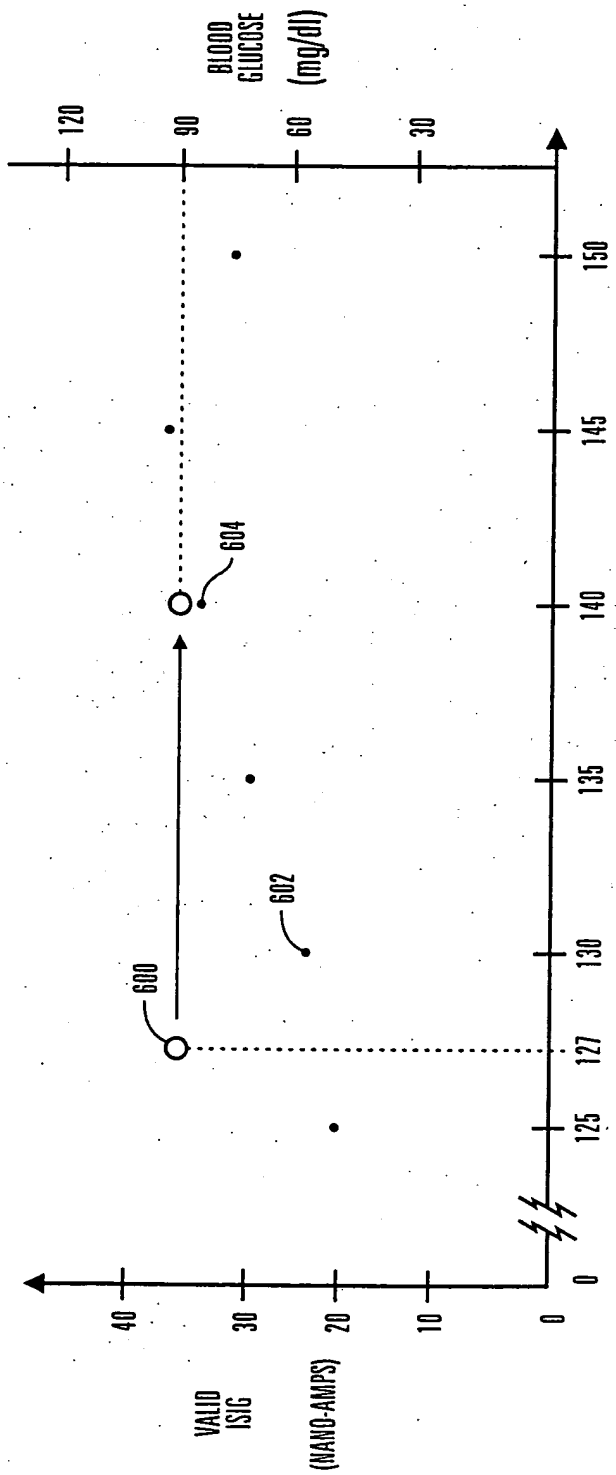

BLOOD GLUCOSE (mg/dl)
120
90
60
30
150
145
140
135
130
127
125
0
TIME (MINUTES)
604
602
600
40
30
20
10
0
VALID ISIG (NANO-AMPS)

FIG. 11

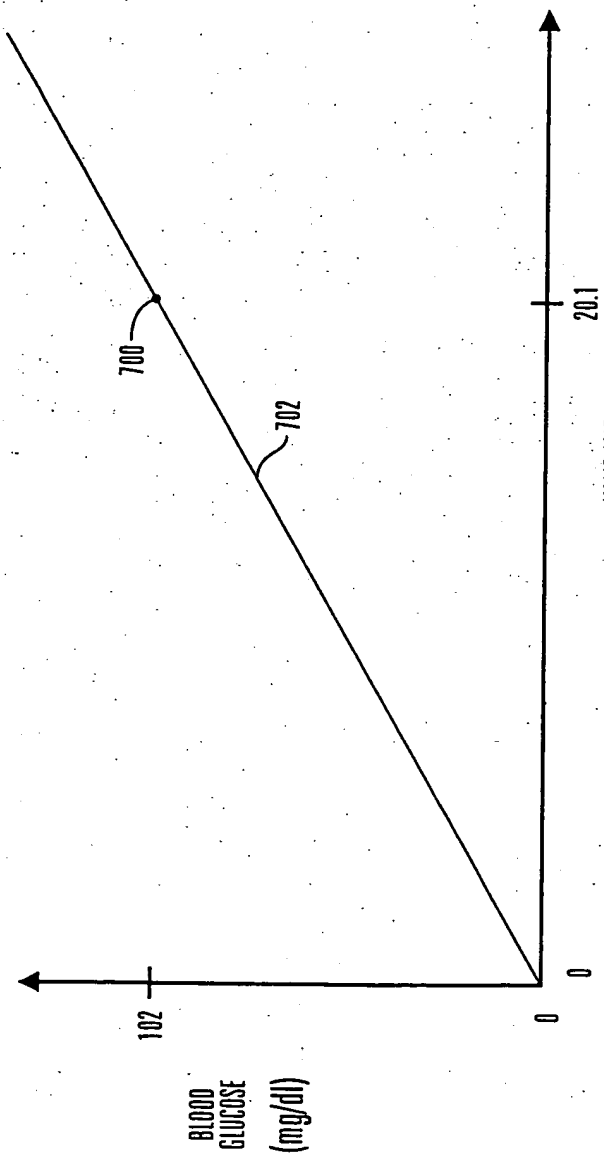



FIG. 12

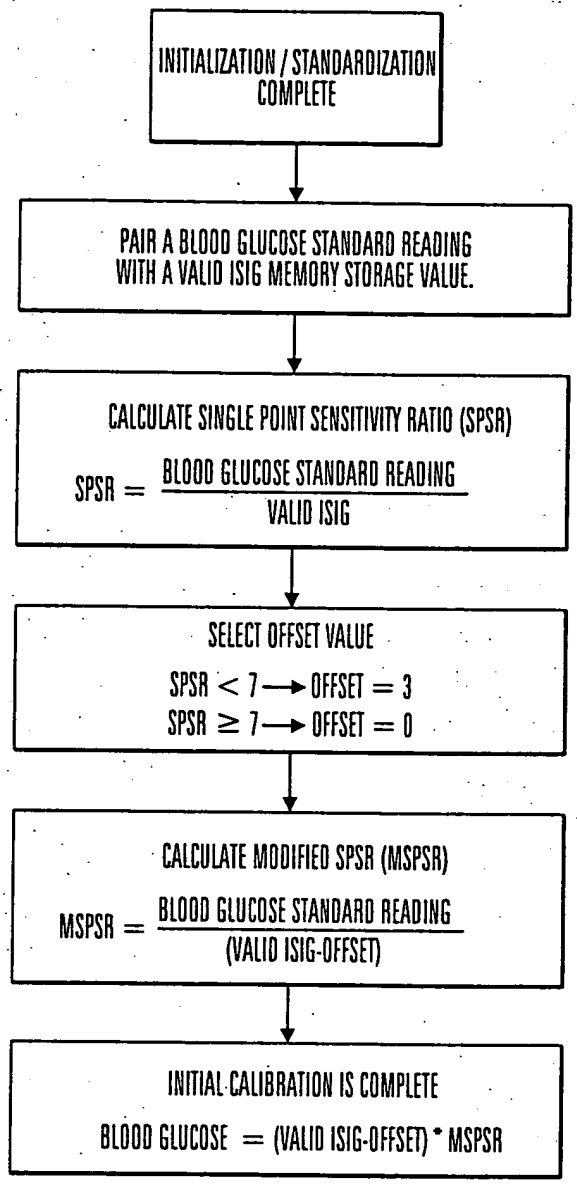

INITIALIZATION / STANDARDIZATION COMPLETE
PAIR A BLOOD GLUCOSE STANDARD READING WITH A VALID ISIG MEMORY STORAGE VALUE.
CALCULATE SINGLE POINT SENSITIVITY RATIO (SPSR)
SPSR = BLOOD GLUCOSE STANDARD READING / VALID ISIG
SELECT OFFSET VALUE
SPSR < 7 → OFFSET = 3
SPSR ≥ 7 → OFFSET = 0
CALCULATE MODIFIED SPSR (MSPSR)
MSPSR = BLOOD GLUCOSE STANDARD READING / (VALID ISIG-OFFSET)
INITIAL CALIBRATION IS COMPLETE
BLOOD GLUCOSE = (VALID ISIG-OFFSET) * MSPSR

FIG. 13

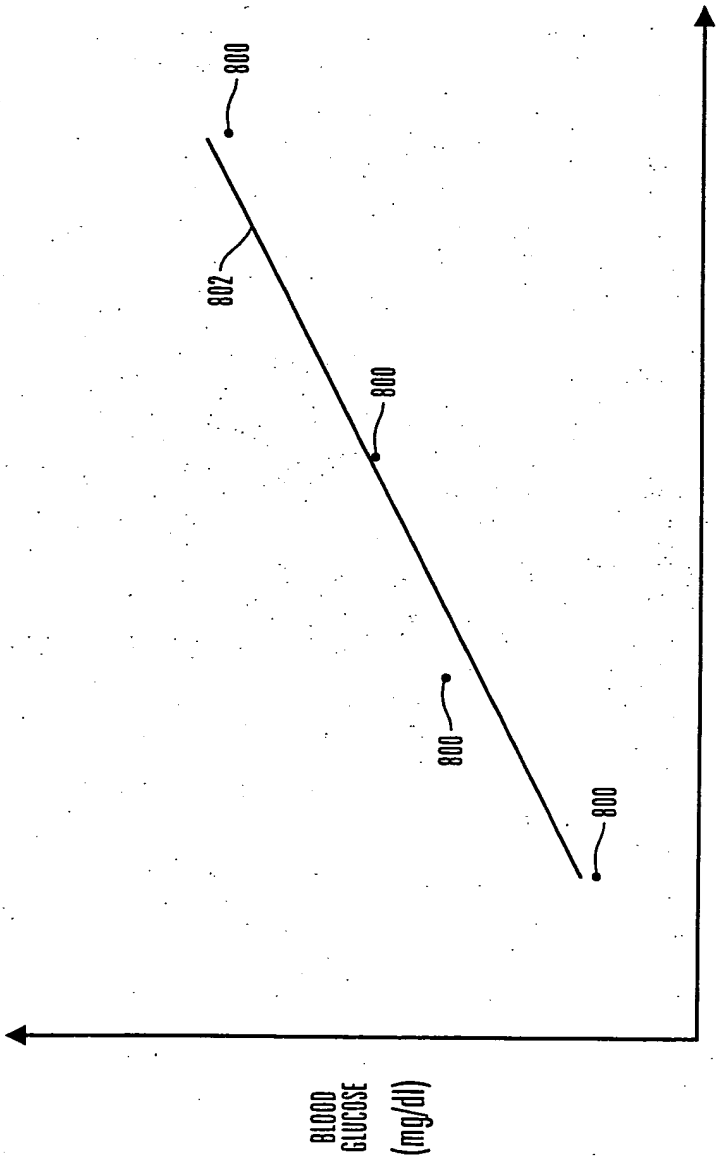



FIG. 14

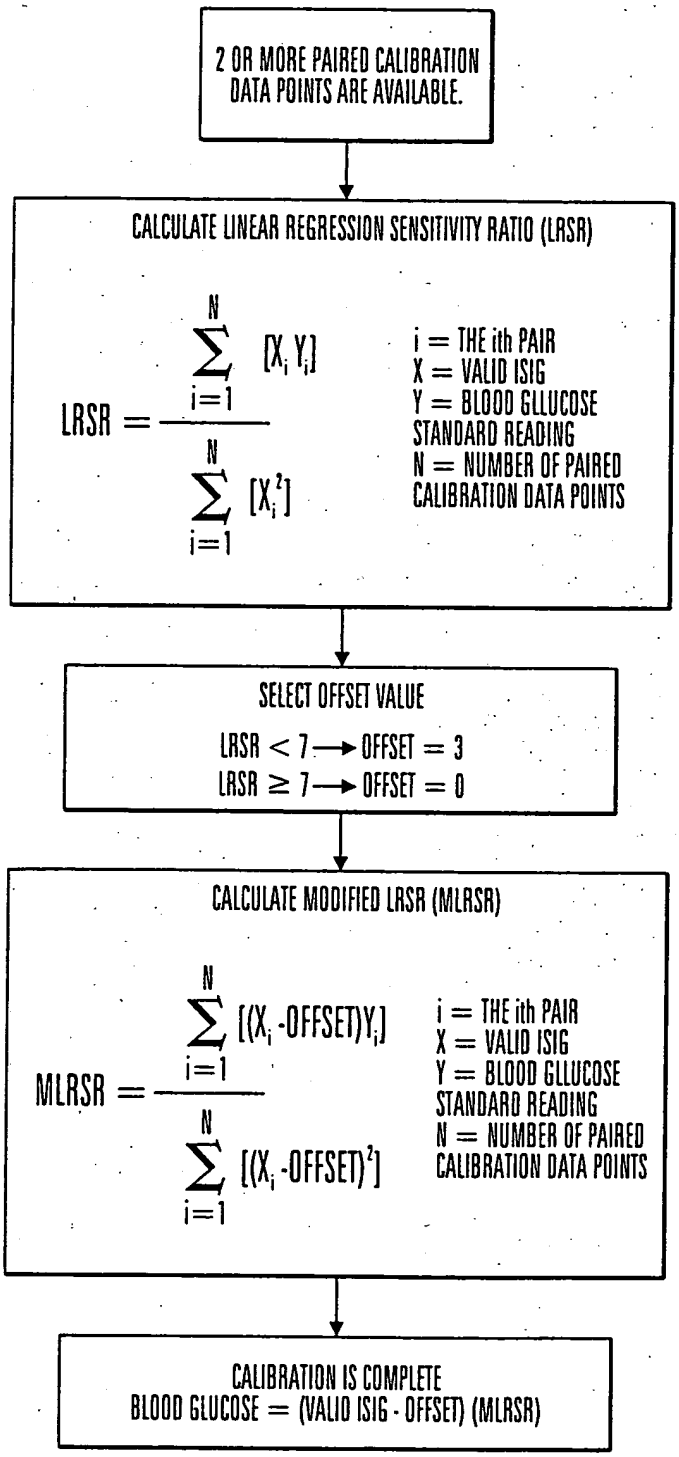
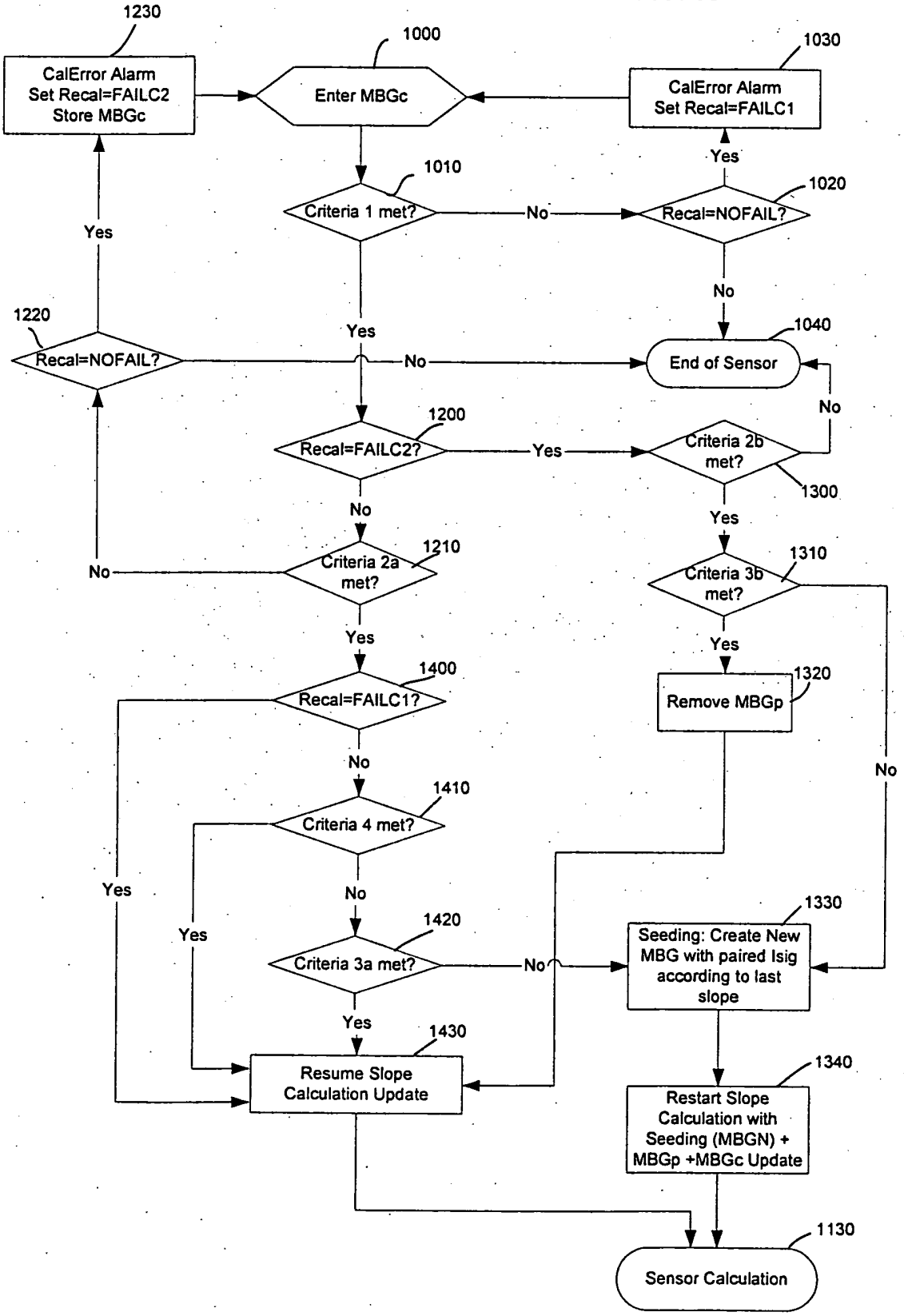

2 OR MORE PAIRED CALIBRATION DATA POINTS ARE AVAILABLE.
CALCULATE LINEAR REGRESSION SENSITIVITY RATIO (LRSR)
$LRSR = \frac{\sum_{i=1}^{N} [X_i Y_i]}{\sum_{i=1}^{N} [X_i^2]}$
i = THE ith PAIR
X = VALID ISIG
Y = BLOOD GLUCOSE STANDARD READING
N = NUMBER OF PAIRED CALIBRATION DATA POINTS
SELECT OFFSET VALUE
LRSR < 7 → OFFSET = 3
LRSR ≥ 7 → OFFSET = 0
CALCULATE MODIFIED LRSR (MLRSR)
$MLRSR = \frac{\sum_{i=1}^{N} [(X_i - OFFSET)Y_i]}{\sum_{i=1}^{N} [(X_i - OFFSET)^2]}$
i = THE ith PAIR
X = VALID ISIG
Y = BLOOD GLUCOSE STANDARD READING
N = NUMBER OF PAIRED CALIBRATION DATA POINTS
CALIBRATION IS COMPLETE
BLOOD GLUCOSE = (VALID ISIG - OFFSET) (MLRSR)

FIG. 15

FIG. 16


1230
CalError Alarm
Set Recal=FAILC2
Store MBGc
1000
Enter MBGc
1030
CalError Alarm
Set Recal=FAILC1
Yes
1010
Criteria 1 met?
No
1020
Recal=NOFAIL?
No
Yes
1220
Recal=NOFAIL?
Yes
No
1040
End of Sensor
No
1200
Recal=FAILC2?
Yes
Criteria 2b
met?
1300
No
Yes
No
1210
Criteria 2a
met?
1310
Criteria 3b
met?
Yes
Yes
1400
Recal=FAILC1?
1320
Remove MBGp
No
No
1410
Criteria 4 met?
Yes
No
Yes
1420
Criteria 3a met?
No
1330
Seeding: Create New
MBG with paired Isig
according to last
slope
Yes
1430
Resume Slope
Calculation Update
1340
Restart Slope
Calculation with
Seeding (MBGN) +
MBGp +MBGc Update
1130
Sensor Calculation

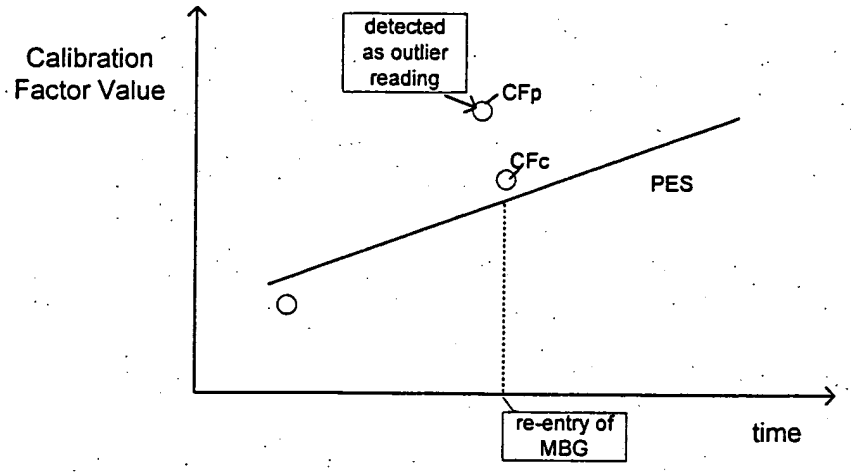



FIG. 17a

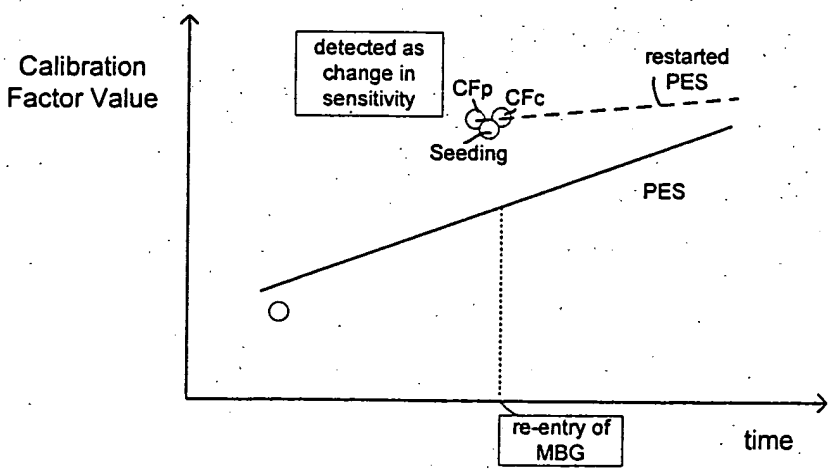



FIG. 17b

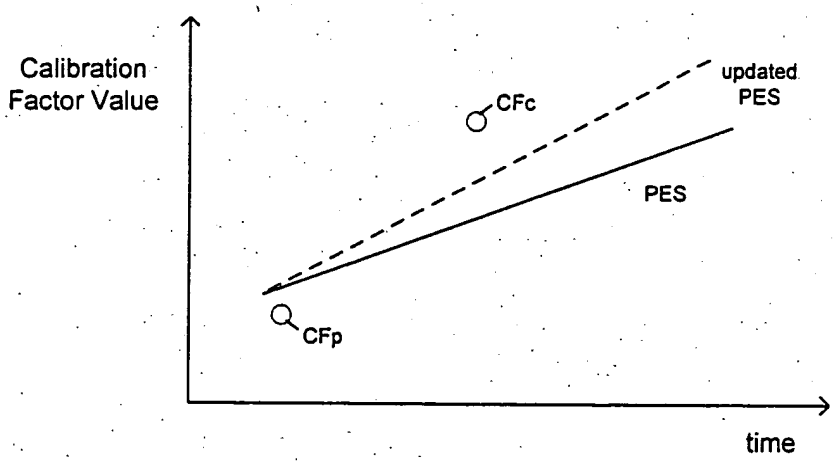



FIG. 18a

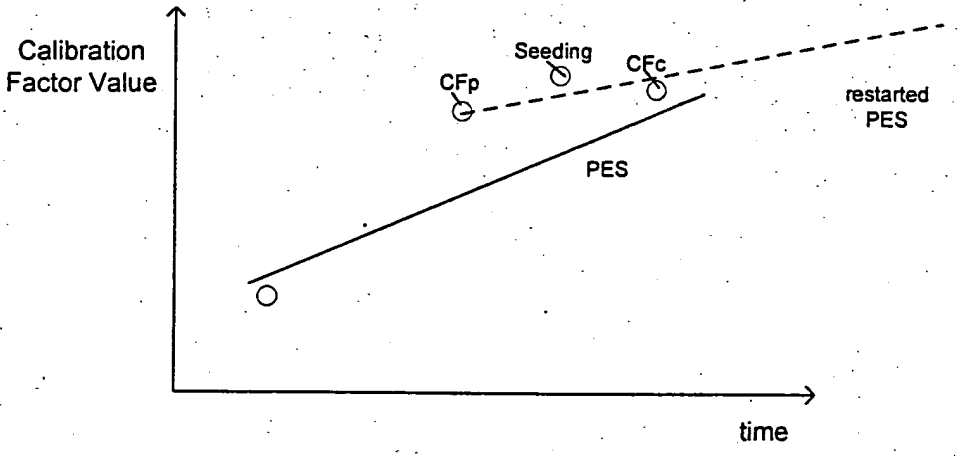



FIG. 18b

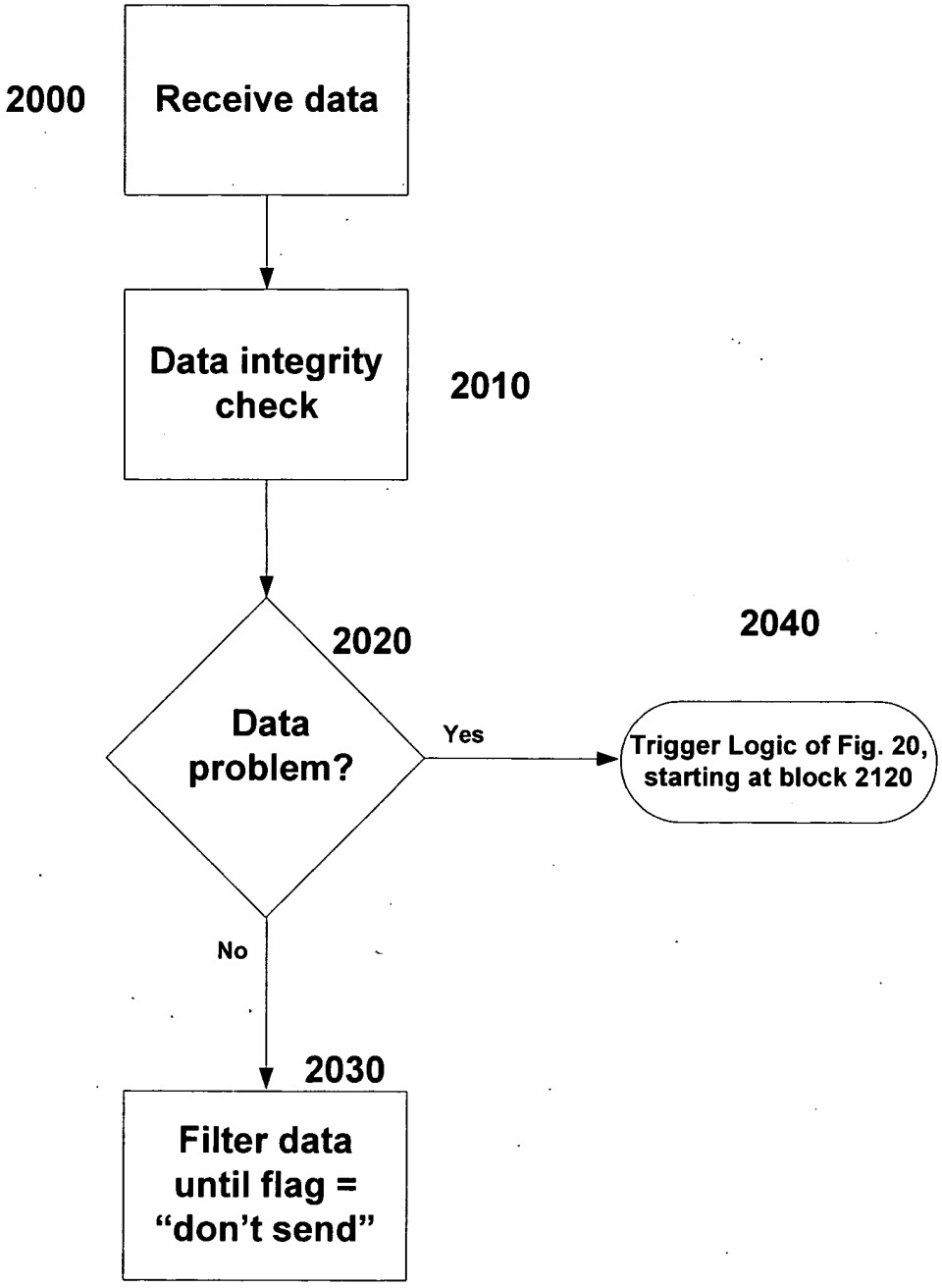

2000
Receive data
Data integrity check
2010
2020
Data problem?
Yes
2040
Trigger Logic of Fig. 20, starting at block 2120
No
2030
Filter data until flag = "don't send"

FIG. 19

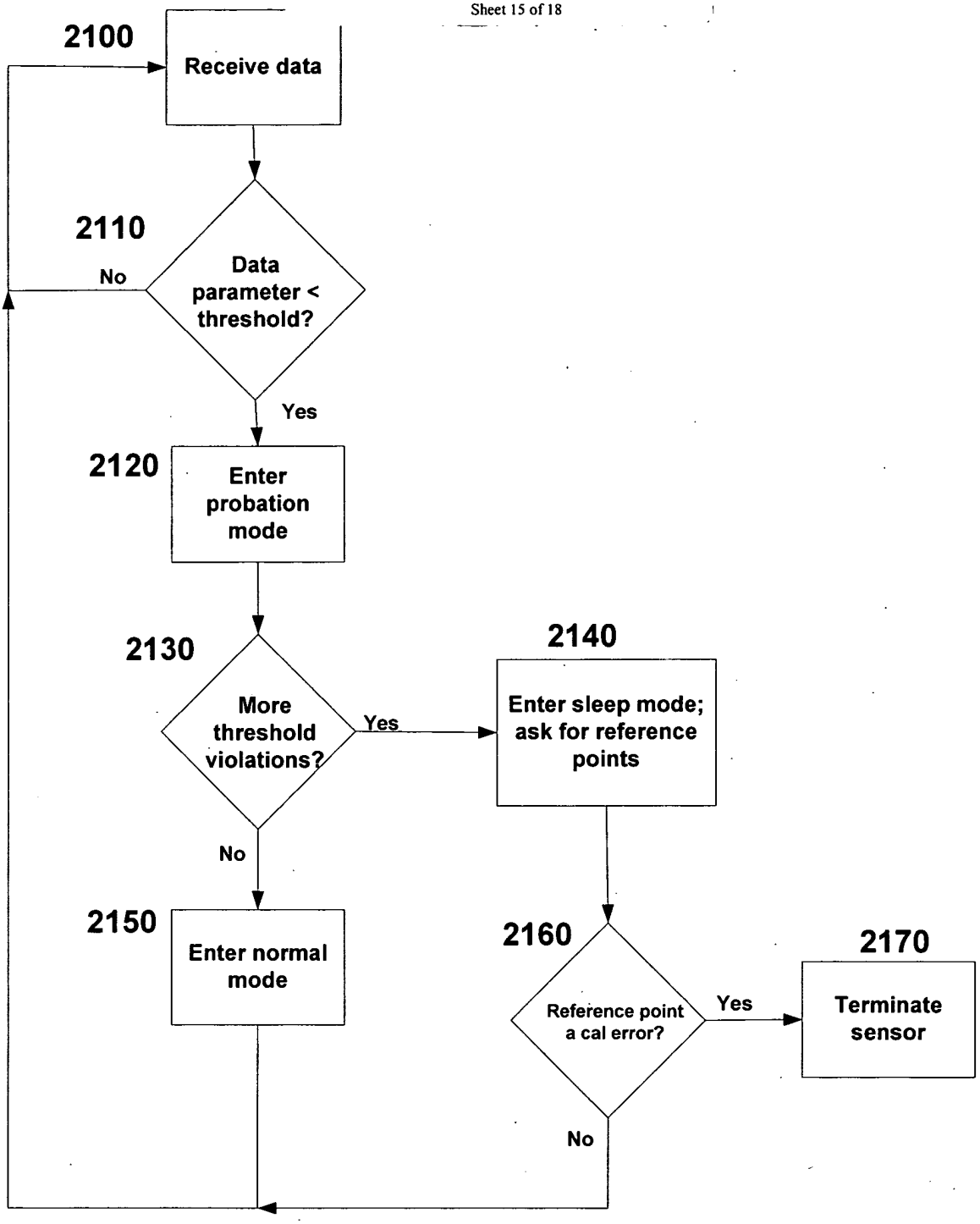

2100
Receive data
2110
Data parameter < threshold?
No
Yes
2120
Enter probation mode
2130
More threshold violations?
Yes
2140
Enter sleep mode; ask for reference points
No
2150
Enter normal mode
2160
Reference point a cal error?
Yes
2170
Terminate sensor
No

FIG. 20

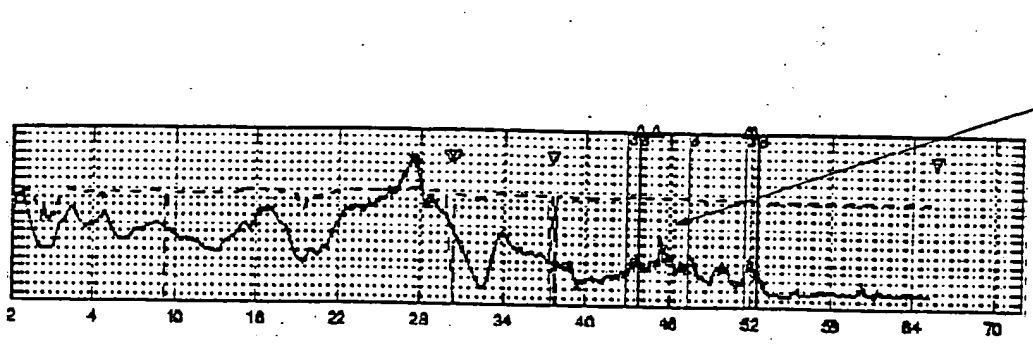



Fig. 21a

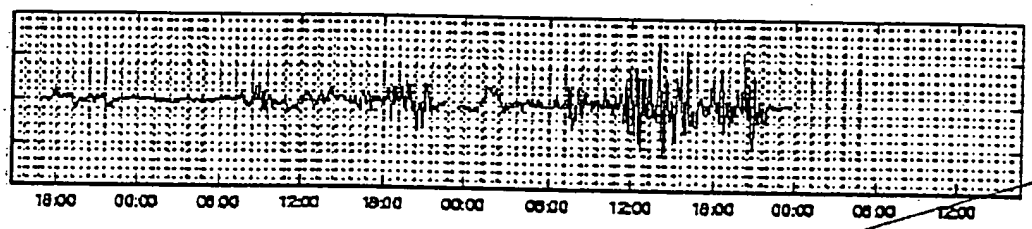



Fig. 21b

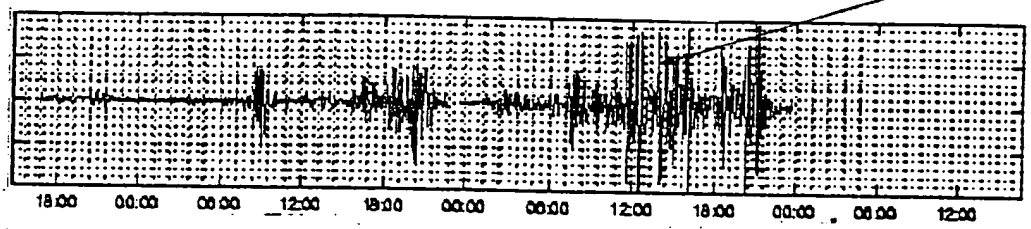



Fig. 21c

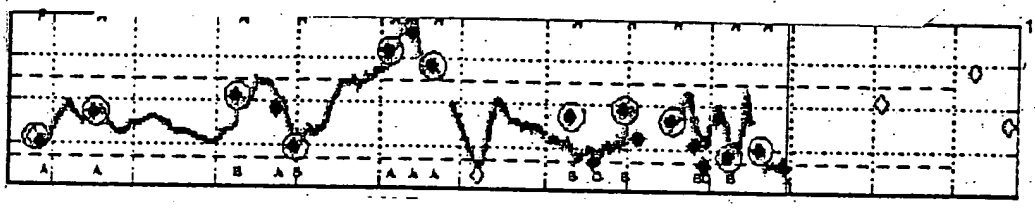


Fig. 21d

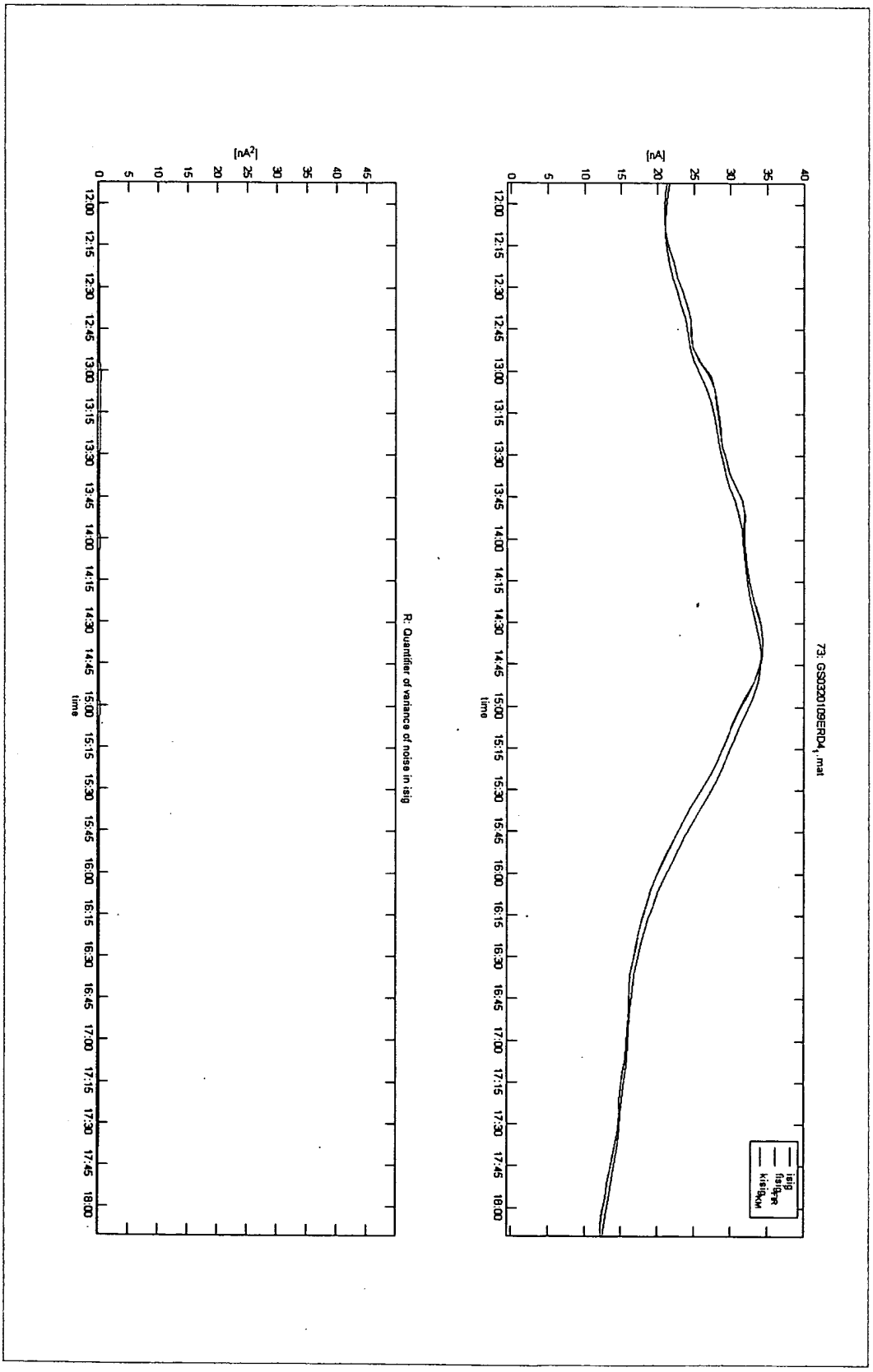
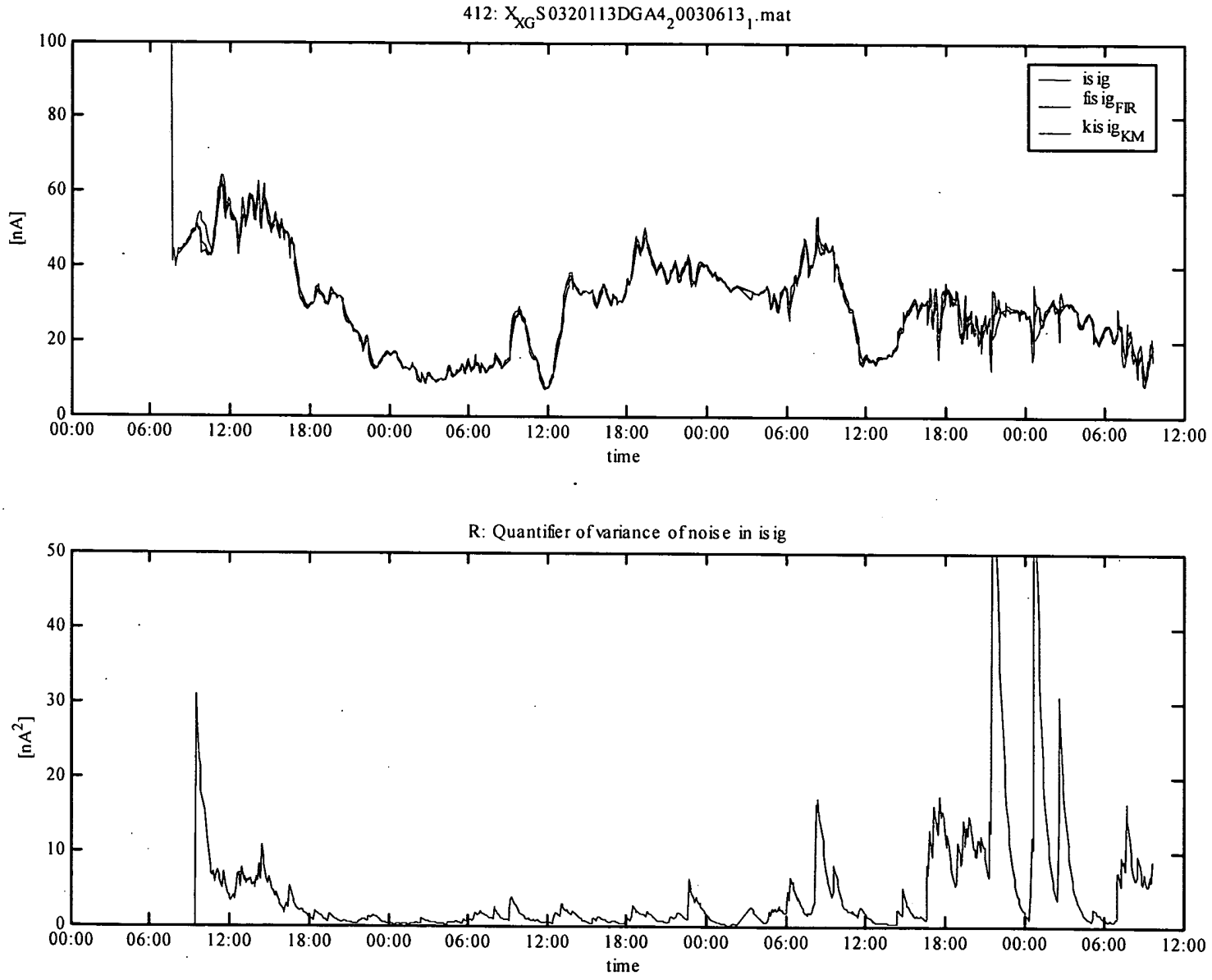

73: GS03201109ERD4_.mat
[nA]
time
isig
R: Quantifier of variance of noise in isig
[nA²]
time

Figure 22

## Figure 23


412: $X_{XG}S0320113DGA4_20030613_1.mat$
100
80
60
40
20
0
[nA]
is ig
fis $ig_{FIR}$
kis $ig_{KM}$
00:00
06:00
12:00
18:00
00:00
06:00
12:00
18:00
00:00
06:00
12:00
18:00
00:00
06:00
12:00
time
R: Quantifier of variance of noise in is ig
50
40
30
20
10
0
[$nA^2$]
00:00
06:00
12:00
18:00
00:00
06:00
12:00
18:00
00:00
06:00
12:00
18:00
00:00
06:00
12:00
time